TANDEM - Subcutaneous Tocilizumab in monotherapy or in combination with csDMARD in patients with moderate to severe active Rheumatoid Arthritis and followed by hospital and office-based rheumatologists: Non-interventional study to describe realworld drug retention rate of the biotherapy at 1 year

Head :Medical data center

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General

Identification

Detailed name	Subcutaneous Tocilizumab in monotherapy or in combination with csDMARD in patients with moderate to severe active Rheumatoid Arthritis and followed by hospital and office-based rheumatologists: Non-interventional study to describe realworld drug retention rate of the biotherapy at 1 year
Sign or acronym	TANDEM
CNIL registration number, number and date of CPP agreement, AFSSAPS (French Health Products Safety Agency) authorisation	ML29256

General Aspects

Medical area	Rheumatology
Study in connection with Covid-19	No
Pathology (details)	Rheumatoid arthritis
Health determinants	Medicine
Keywords	Tocilizumab

Scientific investigator(s) (Contact)

Name of the director	Medical data center
Email	data_sharing_france@roche.com
Organization	Roche SAS

Collaborations	
Participation in projects, networks and consortia	No
Funding	
Funding status	Private
Governance of the database	
Sponsor(s) or organisation(s) responsible	Roche SAS
Organisation status	Private
Presence of scientific or steering committees	Yes
Additional contact	
Main features	
Type of database	
Type of database	Study databases
Study databases (details)	Cohort study
Database recruitment is carried out by an intermediary	A selection of health institutions and services
Database recruitment is carried out as part of an interventional study	No
Database objective	
Main objective	Primary objective : To assess the drug retention rate of TCZ sc at 12 months under real-world conditions in patients with moderate to severe active RA followed by hospital- and office-based rheumatologists Secondary objectives : - To assess the drug retention rate of TCZ sc at 6 and 18 months. - To compare the drug retention of TCZ sc in monotherapy and in combination with MTX or other csDMARD. - To describe steroid dosing after introduction of TCZ sc with a stratification on the use of MTX or other csDMARDs at 6, 12 and 18 months. - To assess adherence to TCZ sc using a French

	version of the Compliance Questionnaire for Rheumatology 5 (CQR5) and patient diary at 6, 12 and 18 months. - To evaluate the French version of the CQR5 by assessing the correlation with the data collected from the patient diary data. - To describe the modalities of use of TCZ sc. - To describe the management of RA and patients' healthcare pathway between hospital- and office-based rheumatologists. - To describe the efficacy of TCZ sc under real-world conditions of use. - To describe the characteristics of patients treated with TCZ sc and the characteristics of the involved physicians. - To assess the tolerability profile of TCZ sc under real-world conditions of use. - To describe the quality of life (QoL) in patients receiving TCZ sc under real-world conditions of use.
Inclusion criteria	Inclusion criteria : - Patients at least 18 years-old. - Patients with moderate to severe RA not previously treated with TCZ (iv or sc), for whom the rheumatologists have decided to initiate TCZ sc treatment as monotherapy or in combination with another csDMARD. - Patients who have been informed verbally and in writing about this study, who do not object to their data being electronically processed or subjected to data quality control and who have signed the consent form.
Population type	
Age	Adulthood (19 to 24 years) Adulthood (25 to 44 years) Adulthood (45 to 64 years) Elderly (65 to 79 years) Great age (80 years and more)
Population covered	Sick population
Pathology	M05-M14 - Inflammatory polyarthropathies
Gender	Male Woman
Geography area	National
Data collection	
Dates	

Date of first collection (YYYY or MM/YYYY)	2015
Date of last collection (YYYY or MM/YYYY)	2018
Size of the database	
Size of the database (number of individuals)	< 500 individuals
Details of the number of individuals	286
Data	
Database activity	Data collection completed
Type of data collected	Clinical data
Clinical data (detail)	Medical registration
Details of collected clinical data	Eligibility /Consent form ; Inclusion criteria / Exclusion criteria ; Status ; Demography ; History of Rheumatoid Arthritis and Medical history ; Prior treatments ; Activity of RA : ESR / CRP ; Treatment with RoActemra® sc ; Hospitalization for RA ; Early termination ; Concomitant Treatment ; Adverse Events ; CQR-5/CQ5D/HAQDI.
Presence of a biobank	No
Procedures	
Data collection method	eCRF
Classifications used	CDISC
Quality procedure(s) used	GCP/GVP
Participant monitoring	Yes
Monitoring procedures	Monitoring by contact with the referring doctor
Links to administrative sources	No
Promotion and access	
Promotion	
Access	

Dedicated website	https://www.roche.fr/fr/innovation-recherche-medicale/data-sharing-portail-d-information-partage-des-donnees.html
Access to aggregated data	Access on specific project only
Access to individual data	Access on specific project only